NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ALLYN TURNOFSKY, *Individually and on behalf of All Others Similarly Situated*, Plaintiff, v. **ELECTROCORE, INC., *et al*.,** Defendants.	Civil Action No. 19-18400 (ZNQ) (TJB) **OPINION**

QURAISHI, District Judge

THIS MATTER comes before the Court upon a Motion to Dismiss the Second Amended Complaint ("the Motion") filed by Defendants electroCore, Inc. ("electroCore"), Francis R. Amato ("Amato"), Glenn S. Vraniak ("Vraniak"), Brian Posner ("Posner"), Carrie S. Cox ("Cox"), Michael G. Atieh ("Atieh"), Joseph P. Errico ("J. Errico"), Nicholas Colucci ("Colucci"), Thomas J. Errico ("T. Errico"), Trevor J. Moody ("Moody"), Michael W. Ross ("Ross"), David M. Rubin ("Rubin"), James L.L. Tullis ("Tullis"), Stephen L. Ondra ("Ondra"), Core Ventures II, LLC ("CV II"), Core Ventures IV, LLC ("CV IV"), Evercore Group L.L.C. ("Evercore"), Cantor Fitzgerald & Co. ("Cantor Fitzgerald"), JMP Securities ("JMP") BTIG, LLC ("BTIG") (collectively, "Defendants") pursuant to Fed. R. Civ. P. 12(b)(6). (ECF No. 63.) Defendants filed a brief in support of the Motion. ("Moving Br.", ECF No. 63-1). Lead Plaintiff Carole Tibbs ("Plaintiff") opposed the Motion. ("Opp'n Br.", ECF No. 64.) Defendants filed a reply. ("Reply Br.", ECF No. 65.) The Court has carefully considered the parties' submissions and decides the Motion

without oral argument pursuant to Federal Rule of Civil Procedure[1] 78 and Local Civil Rule 78.1. For the reasons set forth below, the Court will GRANT the Motion.

I. PROCEDURAL BACKGROUND

Plaintiff initiated the instant action by filing a Complaint against Defendants on September 26, 2019. (ECF No. 1) Plaintiff thereafter filed an Amended Complaint on July 17, 2020. (ECF No. 31.) Defendants filed a Motion to Dismiss the Amended Complaint. (ECF No. 41.) The Court granted Defendant's Motion to Dismiss the Amended Complaint and gave Plaintiff leave to file a Second Amended Complaint. (ECF No. 56.)

Plaintiff thereafter filed a five-count Second Amended Complaint ("SAC", ECF No. 60) alleging violations of Section 11 of the Securities Act, 15 U.S.C. § 77k (Count I); Section 12(a)(2) of the Securities Act, 15 U.S.C. § 77*l* (Count II); Section 15 of the Securities Act, 15 U.S.C. § 77*o* (Count III); Section 10(b) of the Securities Exchange Act, 15 U.S.C. § 78j(b), and SEC Rule 10b-5 (Count IV); and Section 20(a) of the Securities Exchange Act, 15 U.S.C. § 78t(a) (Count V).

II. FACTUAL BACKGROUND[2]

Defendant electroCore Inc. ("electroCore" or "the Company") is a bioelectronic medicine company. (SAC ¶ 1.) Plaintiff asserts claims arising out of electroCore's offering documents (the "Offering Documents") under Sections 11, 12(a)(2), and 15 of the Securities Act against electroCore, Amato, Vraniak, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, Ross, Rubin, Tullis, CV II , CV IV, Evercore, Cantor Fitzgerald, JMP, and BTIG (collectively, "Securities Act Defendants"). (*Id*. ¶¶ 10, 44, 45.) Plaintiff also asserts claims arising under Sections 10(b) and 20(a) of the Securities Exchange Act against electroCore, Amato, Vraniak,

[1] For the sake of brevity, all references herein to "Rule" will be to the Federal Rules of Civil Procedure.
[2] For purposes of this motion, the Court will take all facts alleged in the Amended Complaint as true. *Kulwicki v. Dawson*, 969 F.2d 1454, 1462 (3d Cir. 1992).

Posner, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, and Tullis (collectively, "Exchange Act Defendants").[3] (*Id*. ¶¶ 11, 46.)

Plaintiff relies on statements of several confidential witnesses to support her claims (*See, e.g.*, *id* ¶¶ 69, 76–81, 83–84, 90–107, 109–115.) Specifically, Plaintiff relies heavily upon statements made by CW3, a confidential witness who was employed by electroCore from April 2015 to January 2019 as Vice President of Payer and Provider Strategies, to support her claims that there were no agreements directly with commercial insurance payers at the time of the Company's initial public offering ("IPO"). (*Id*. ¶ 6, 76.)

The Court will rely on the facts set forth in its prior Opinion for the background facts of the Company and its insurance coverage issues. (ECF No. 56 at 2–3.)

A. Violations of Sections 11, 12(a)(2) and 15 of the Securities Act

Defendants Amato, Vraniak, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, Ross, Rubin, and Tullis each participated in the preparation of and signed (or authorized the signing of) the Registration Statement and/or an amendment thereto, and the issuance thereof. (*Id.* ¶ 125.) By virtue of their positions with the Company, Defendants Amato, Vraniak, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, Ross, Rubin, and Tullis possessed the power and authority to control the contents of electroCore's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and market investors. (*Id.* ¶ 126.)

In the "run-up to the IPO," Defendants Evercore, Cantor Fitzgerald, JMP, and BTIG ("Underwriter Defendants") assisted in (i) the preparation and presentation of any "road show" materials designed to induce investment in the Company; (ii) conducted due diligence on the

[3] Amato, Vraniak, Posner, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, Ross, Rubin, and Tullis are sometimes referred to herein collectively as the "Individual Defendants."

Company, including, inter alia, access to confidential corporate information concerning electroCore's business operations unknown to the investing public; and (iii) consulted with Company management regarding the content of the Offering Documents. (*Id.* ¶ 127.) Underwriter Defendants assisted electroCore and Individual Defendants in planning the IPO. (*Id.* ¶ 128.) Plaintiff claims in the SAC that the Underwriter Defendants were required to conduct an adequate and reasonable investigation into the business and operations of the Company to participate in the IPO, a process known as a "due diligence investigation." (*Id.*) During the course of the due diligence investigation, Underwriter Defendants had continual access to confidential corporate information concerning electroCore's operations and financial prospects. (*Id.*)

1. electroCore's IPO

electroCore filed its initial confidential draft registration statement on Form DRS with the SEC on February 13, 2018. (*Id.* ¶ 130.) Amended Forms DRS were then filed on April 2, 2018 and May 11, 2018, with the first registration statement on Form S-1 filed with the SEC on May 21, 2018. (*Id.*) electroCore filed amendments to the Form S-1 on June 5, 2018, June 11, 2018, and June 15, 2018 (collectively, the "Registration Statement"). (*Id.*) The Registration Statement was declared effective by the SEC on June 21, 2018. (*Id.*)

On June 25, 2018, electroCore filed with the SEC a prospectus pursuant to Rule 424(b)(4) (the "Prospectus"), commencing its IPO of 5.2 million shares of common stock at a price of $15.00 per share. (*Id.* ¶ 131.) The Offering Documents stated that the intended use of the IPO proceeds was to be as follows: (i) $35 million to fund commercialization of products; (ii) $10 million to fund expansion of its clinical programs; (iii) $3 million to fund the build out of a specialty distribution channel for the launch of gammaCore Sapphire in the third quarter of 2018; and (iv) the remaining balance for working capital and other corporate purposes. (*Id.* ¶ 131.)

On June 28, 2018, electroCore announced that the Underwriter Defendants had chosen to exercise their option to sell an additional 780,000 shares. (*Id.* ¶ 132.) In total, electroCore issued and sold 5,980,000 shares of common stock, reaping net proceeds of approximately $77.7 million. (*Id.*)

2. electroCore's Offering Documents

Plaintiff alleges in the SAC that the Offering Documents "stressed and repeated no less than six times" that the Company had agreements in place with commercial payers providing for reimbursement of gammaCore as a pharmacy benefit and giving the Company access to 17 million lives at the time of the IPO with access of up to 45 million lives expected in the near future despite the fact that the Company had no direct agreements with commercial insurance company and only two limited agreements with PBM's. (*Id.* ¶ 134.)

The Offering Documents explained under a section titled "Coverage and Reimbursement" the following:

> While some commercial payors may provide coverage under their pharmacy benefit plans, other payors, including governmental and private insurers, may not be willing or authorized to provide coverage for our therapy under pharmacy plans that more commonly cover prescription drug products. These payors may require us to seek coverage for gammaCore as a medical supply or item of durable medical equipment, which could result in the application of different pricing, reimbursement, and patient cost-sharing policies to our products.

(*Id.* ¶ 135).

The Offering Documents' risk disclosures speak of vague future contingencies and risks regarding the possibility that that third party payers may not agree to cover gammaCore. (*Id.* ¶ 137.) The SAC reads that these disclosures "misrepresent or omit material present facts regarding existing coverage." (*Id.*)

Plaintiff claims that the disclosed risks were not a mere possibility, but were in fact occurring. (*Id.* ¶ 139.)

Plaintiff further claims that the Offering Documents were materially untrue and misleading because they failed to meet the requirements of Item 303 of SEC Regulation S-K. (*Id.* ¶ 140.) Plaintiff also claims that the Securities Act Defendants failed to adequately describe the risks in the "Risk Factors" section of the Offering Documents, violating Item 503(c) of the SEC Regulation S-K. (*Id.* ¶ 141.)

3. Events and Disclosures Following the Offering

The CVS agreement did not begin coverage until the first quarter of 2019. (*Id.* ¶ 143.) On May 14, 2019, electroCore began to disclose the specific difficulties it faced in obtaining commercial insurance coverage. (*Id.* ¶ 144.) On May 29, 2019, the Company announced a comprehensive redeployment and cost reduction plan and, on June 10, 2019, the Company announced that defendant Amato would be stepping down as CEO. (*Id.*) By the commencement of this action, electroCore stock was trading as low as $1.25 per share, a nearly 92% decline from the $15.00 per share IPO price. (*Id.* ¶ 145.)

B. Violations of Sections 10(b) and 20(a) of the Securities Exchange Act

The Securities Exchange Act claims are brought against Defendants electroCore, Amato, Vraniak, Posner, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, and Tullis ("Exchange Act Defendants"). (*Id.* ¶ 177.)

electroCore is the issuer of the statements within the Offering Documents, and Amato, Vraniak, J. Errico, T. Errico, Cox, Colucci, Moody, and Tullis signed their names or authorized the signing of their names to those statements. (*Id.* ¶ 178.)

On November 13, 2018, the Company issued a press release and a Form 8-K with the SEC, signed by Vraniak, titled "electroCore, Inc. Announces Third Quarter Financial Results" (the "November 2018 Press Release"). (*Id.* ¶ 179.) The November 2018 Press Release highlighted that they were continuing discussions and negotiations for payor coverage for an additional 90 million lives and that the Company's decrease in net sales was due to prescriptions being dispensed under their patient voucher program. (*Id.* ¶ 179.)

In an earnings conference call on November 13, 2018, Amato stated that they had multiple reimbursement agreements in place, including the CVS agreement which would provide access to approximately 30 million of the 65 million U.S. individuals managed by CVS. (*Id.* ¶ 180–81.) Josh Schimmer, an analyst with Evercore ISI, inquired as to paid prescription growth and the Company's ability to reach agreements for reimbursement with payers. (*Id.* ¶ 182.) Amato responded that with respect to the Company's confidence with PBMs, they were awaiting a contract proposal with OptumRX, and that they had already negotiated with Express Scripts ("ESI"), a PBM. (*Id.*) Vraniak discussed the financial results and the voucher program, indicating that the degrees in revenue was primarily due to the voucher program. (*Id.* ¶ 183.)

On November 14, 2018, electroCore filed its quarterly report Form 10-Q with the SEC for the quarter ending on September 30, 2018 (the "3Q18 10-Q"), signed by Amato and Vraniak. (*Id.* ¶ 184.) Amato and Vraniak also signed the certifications pursuant to the Sarbanes-Oxley Act of 2002, which attested to the accuracy of the financial reporting and the disclosure of any material changes to the Company's internal control over financial reporting. (*Id.*)

The 3Q18 10-Q stated that there were "no material changes during the three months ended September 30, 2018 to the risk factors disclosed in our prospectus dated June 21, 2018, filed with the SEC[.]" (*Id.* ¶ 185.) Plaintiff claims the statements made in the November 2018 Press Release

and on the 3Q18 10-Q were materially false and/or misleading and failed to disclose material adverse facts. (*Id.* ¶ 186.)

On March 27, 2019, electroCore issued a press release to a Form 8-K filed with the SEC and signed by Vraniak titled "electroCore Announces Fourth Quarter and Full Year 2018 Financial Results," announcing the Company's financial results for the quarter and year ended December 31, 2018 (the "March 2019 Press Release"). (*Id.* ¶ 187.) In the March 2019 Press Release, Amato stated that "[d]uring the fourth quarter, we continued to execute on our commercial growth plan, led by our ongoing progress toward increasing covered lives through productive discussions with national and regional payers." (*Id.*)

The Company also held an earnings conference call on March 27, 2019, which was attended by Amato, Vraniak, and J. Errico. (*Id.* ¶ 188.) On that call, Amato indicated the Company's success, and that electroCore remained "on track to achieve 75 million covered lived by the middle of this year and 100 million by the end of the year." (*Id.*) Amato commented on the code issue with ESI, stating that they were having "logistical challenges with one of the compendium organizations making the availability of our product codes to pharmacy benefit manages a challenge. These issues have especially affected our negotiations with Express Scripts." (*Id.* ¶ 189.) Vraniak commented on the purported demand driving voucher program, indicating that that the Company "continue[d] to believe these programs [were] accomplishing [their] objectives of providing patient therapy at no charge . . . ." (*Id.* ¶ 190.) An analyst from Evercore ISI questioned the Company's cash burn, and Amato reassured investors that it was not an issue. (*Id.* ¶ 191.)

Plaintiff claims that the statements within the March 2019 Press Release and the related earnings conference call were materially false and/or misleading and failed to disclose material adverse facts. (*Id.* ¶ 192.)

On March 28, 2019, the Company filed its 2018 form 10-K with the SEC, signed by Amato, Vraniak, J. Errico, T. Errico, Cox, Atieh, Colucci, Moody, Ondra, and Tullis, affirming the information provided in the March 2019 Press Release. (*Id.* ¶ 193.) Amato and Vraniak also signed the certifications pursuant to the Sarbanes-Oxley Act of 2002. (*Id.*) The 2018 Form 10-K repeatedly discussed electroCore's current payer agreements and access to commercial lives and ongoing negotiations. (*Id.* ¶ 194.) The 2018 Form 10-K also discussed the voucher program instituted during 2018. (*Id.* ¶ 195.) Plaintiff claims the Form 10-K statements were materially false and misleading and omitted to disclose information necessary to make its statements not misleading. (*Id.* ¶ 196.)

The Form 10-K risk disclosures speak of "vague future contingencies and risks regarding the possibility that third party payers may not agree to cover gammaCore." (*Id.* ¶ 197.) Plaintiff alleges that the disclosed risks were in fact occurring and would lead to modifications to the Company's commercialization strategy and have a material adverse effect on the sales of gammaCore. (*Id.* ¶ 199.)

On May 14, 2019, electroCore issued a press release, which was also filed with the SEC as an exhibit to a Form 8-K, signed by Posner, titled "electroCore Announces First Quarter 2019 Financial Results" (the "May 2019 Press Release"). (*Id.* ¶ 200.) The May 2019 Press Release highlighted that the Company's first quarter results "[did] not fully reflect the positive impact of new payers that were implemented during the quarter[.]" (*Id.*) The May 2019 Press Release also indicated that the "net cash burn of $16.2 million for the quarter ended March 31, 2019, included

working capital uses of cash due to a $1.6 million increase in inventory and approximately $2.1 million pf payments related to 2018 accrued compensation." (*Id.*) On the earnings conference call, Amato highlighted the Company's "momentum" of gaining patients, physicians and payers, while revealing the "abysmal reimbursement numbers and extra onerous requirements under certain agreements." (*Id.* ¶ 202.) Amato additionally indicated on the call that electroCore was "still in the early days of the implementation of the CVS agreement" and that electroCore "dispensed in the U.S. an additional 1.6 million worth of gammaCore prescriptions through the ongoing promotional programs . . . ." (*Id.*) Amato further admitted that a standard that "'universalizes our codes for inclusion in all pharmacopoeia' was not developed until 2019 and that First Databank, the largest database used by commercial payers, did not agree to 'build[] a third database which [would] include all the codes for [gammaCore]' until 2019." (*Id.* ¶ 203.) Amato additionally admitted that electroCore had a lack of agreements with insurance companies. (*Id.* ¶ 205.)

Defendant Posner stated that the promotional programs were accomplishing their objectives of "'providing patient therapy at no charge, demonstrating the benefits of gammaCore therapies to physicians writing prescriptions, and promoting U.S. commercial payer covers and covers discussions as a result of patient and physical demand.'" (*Id.* ¶ 204.)

Based on this news, electroCore's share price fell $1.58 per share. (*Id.* ¶ 206.)

On May 15, 2019, electroCore filed its quarterly Form 10-Q for the quarter ended March 31, 2019 (the "1Q19 10-Q"), signed by Amato and Posner, and contained their signed certifications pursuant to the Sarbanes-Oxley Act of 2002. (*Id.* ¶ 207.) The 1Q19 10-Q highlighted the voucher program as a mechanism that permitted electroCore to gain access to commercial payers. (*Id.* ¶ 208.) The 1Q19 10-Q indicated that the voucher program "resulted in significant increases in

prescriptions for gammaCore and has prompted negotiations with numerous commercial payers." (*Id.*) Plaintiff claims the statements made within the May 2019 Press Release, the earnings conference call, and the 1Q19 10-Q were materially false and misleading. (*Id.* ¶ 210.)

On May 29, 2019, the Company issued a press release, signed by Posner, titled "electroCore Announces Comprehensive Redeployment and Cost Reduction Plan." (*Id.* ¶ 211.) This press release stated that "'management and the Board of Directors are making significant adjustments to the deployment of personnel and resources across the organization.'" (*Id.*) The May 29, 2019 press release additionally indicated the following: "Inclusive of one-time charges of approximately $350,000 associated with implementation of this plan, the Company's second quarter cash burn is expected to be between $11.0 million and $11.5 million." (*Id.*)

Based on this news, electroCore's share price fell $0.11. (*Id.* ¶ 212.)

On August 13, 2019, the Company issued a price release, signed by defendant Posner, titled "electroCore Announces Second Quarter 2019 Financial Results" (the "August 2019 Press Release"). (*Id.* ¶ 213.) The August 2019 Press Release highlighted that the FDA accepted for review electroCore's 510(k) premarket notification for a new indication for use of gammaCore for the prevention of migraine. (*Id.*) An earnings conference call was also held on August 13, 2019, where Amato reiterated the key points from the August 2019 Press Release and again mentioned the 501(k) submission to the FDA for migraine prevention. (*Id.* ¶ 214.)

According to a confidential witness who served as VP of Clinical Operations based out of the Company's headquarters from December 2019 to August 2019 (CW5), electroCore knew by August 2019 that the FDA had concerns about the "robustness of electroCore's data supporting the use of gammaCore for migraine prevention." (*Id.* ¶ 216.) On September 25, 2019, the Company revealed that the FDA had requested more information and analysis on clinical data for

electroCore's 510(k) submission. (*Id.*) Based on this news, the Company's stock share fell over 23%. (*Id*. ¶217.)

Plaintiff alleges that Exchange Act Defendants acted with scienter in that they "knowingly or recklessly disregarded the information disseminated to the public contained materially false and/or misleading information and omitted material information." (Id. ¶ 223.)

A confidential witness, who served as Director of Clinical Affairs from April 2018 to February 2019 (CW7), commented that because electroCore is a relatively small company, it was "fairly easy to keep senior leaders up-to-date on various aspects of the company, adding that regular meetings were 'a way to talk to everybody' and 'let other departments know what's going on in their department." (*Id*. ¶ 228.) Plaintiff claims that electroCore's Offering Documents and 2018 Form 10-K "touted" the Company's competitive strengths and highly experienced management team, and that Amato, Vraniak, Posner, and J. Errico repeatedly admitted having knowledge of the Company's business. (*Id*. ¶¶ 229, 230.)

Plaintiff additionally alleges that the Individual Defendants had access to certain reports and/or were involved in regular Company meetings, and were "updated on crucial information indicating that the statements made were materially false and/or misleading and omitted material facts." (*Id*. ¶ 233.) Plaintiff relies on statements from confidential witnesses to support this claim. (*See id*. ¶¶ 233–39.)

III. LEGAL STANDARD

"All securities fraud claims are subject to Rule 9(b) [of the Federal Rules of Civil Procedure], which requires [a] plaintiff to 'state with particularity the circumstances constituting fraud or mistake.'" *Williams v. Globus Med., Inc.*, 869 F.3d 235, 240 (3d Cir. 2017) (quoting Fed.

R. Civ. P. 9(b)). "In addition, the [Private] Securities Litigation Reform Act [("PSLRA")] imposes two heightened pleading requirements above the normal Rule 12(b)(6) standard." *Id.* First, the complaint must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1). "This standard requires plaintiffs to plead the who, what, when, where and how: the first paragraph of any newspaper story." *See Inst. Inv. Grp. v. Avaya, Inc.*, 564 F.3d 242, 253 (3d Cir. 2009) (internal quotation marks omitted). Second, "the complaint shall, with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." § 78u-4(b)(2)(A). "Where a plaintiff's [Securities Act] claims are not grounded in allegations of fraud, the liberal notice pleading requirements of Rule 8 [of the Federal Rules of Civil Procedure] apply" to those claims. *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 270 (3d Cir. 2006).

IV. DISCUSSION

As a preliminary matter, the Court has subject matter jurisdiction over these claims. Further, Rule 8 of the Federal Rules of Civil Procedure applies to Plaintiff's Securities Act claims. Where Securities Act claims allege ordinary negligence and are pled separately from Securities Exchange Act claims, "[t]hat is enough to avoid triggering Rule 9(b)." *See Suprema*, 438 F.3d at 273. Plaintiff's Securities Act claims "expressly disclaim[] any allegations that could be construed as alleging fraud or intentional or reckless misconduct." (SAC ¶ 123.) Therefore, the Court applies Rule 8, not Rule 9(b) or the PSLRA's heightened pleading standard, to Plaintiff's Securities Act claims.

A. Counts One and Two: Violations of Sections 11 and 12(a)(2) of the Securities Act

Section 11 of the Securities Act creates a private cause of action in cases where a registration statement "contain[s] an untrue statement of a material fact or omit[s] to state a material fact required to be stated therein or necessary to make the statements therein not misleading." 15 U.S.C. § 77k. Similarly, to state a claim under section 12(a)(2), a plaintiff must allege that they purchased securities pursuant to a materially false or misleading "prospectus or oral communication." 15 U.S.C.A. § 77*l*; *In re Adams Golf, Inc. Sec. Litig*., 381 F.3d 267, 273 (3d Cir. 2004).

"Section 11 imposes near-strict liability for untruths and omissions made in a registration statement." *Obasi Inv. LTD v. Tibet Pharms., Inc.,* 931 F.3d 179, 182 (3d Cir. 2019). An omitted fact is material where "there is a substantial likelihood that a reasonable [investor] would consider it important." *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 196 (2015) (quoting *TSC Indus., Inc. v. Northway*, Inc., 426 U.S. 438, 449 (1976)). There is no "affirmative duty to disclose any and all material information. Disclosure is required only when necessary to make . . . statements made, in light of the circumstances under which they were made, not misleading." *See Williams*, 869 F.3d at 241 (internal quotation marks omitted) (Securities Exchange Act case). "[W]hether a statement is 'misleading' depends on the perspective of a reasonable investor: The inquiry . . . is objective." *Omnicare*, 575 U.S. at 186–87.

1. Types of Payor Agreements electroCore Had in Place

Defendants argue that Plaintiff is unable to identify a single statement within any public statement that was false when made. (Moving Br. at 2.) Defendant argues that electroCore's Registration Statement's reference to "commercial payors" did not refer to insurance companies only, but also included PBMs. (*Id.* at 10–11.) Plaintiff argues in opposition that the SAC alleges

how and why the Registration Statement's indication that electroCore "had agreements in place with commercial payers was false and misleading." (Opp'n Br. at 8.) Plaintiff maintains that her allegation that electroCore indicated that it had engaged with "commercial insurance payors," claimed that "[a]greements with commercial payors [were] in place," and distinguished that the agreements included "a contract with a PBM," reasonably lead a reader to believe that the other contracts were with insurance companies. (*Id.* at 10.)

In reply, Defendants argue that while Plaintiff can change the words of the Complaint, "Plaintiff cannot change the words of the Prospectus." (Reply Br. at 2.) Defendants contend that Plaintiff attempts to "manufacture a 'misrepresentation' by conflating the term 'commercial payor' with the terms 'insurers' or 'insurance payors.'" (*Id.*) Defendants argue that when the Prospectus referred specifically to insurance companies, it specifically said so by utilizing the term "commercial insurance payor" or "insurer." (*Id.*) Further, Defendant contends that the Prospectus disclosed that agreements with commercial payors were for "reimbursement for gammaCore as a pharmacy benefit" expected to cover "approximately 17 million commercial lives, including a contract with a large PBM." (*Id.* at 3 (citing Prospectus at 130).) Defendants maintain that nothing in the Prospectus supports Plaintiff's contention that it implies the Company had contracts with insurance companies. (*Id.*)

The Registration Statement explained that electroCore had

> agreements in place with commercial payors that [electroCore] believe[d], based on [its] estimates, w[ould] provide for reimbursement for gammaCore as a pharmacy benefit for approximately 17 million commercial lives[,] with such number expected to increase to as many as 45 million lives under these agreements over the next several calendar quarters.

(Offering Documents at 2.)

The SAC alleges that electroCore misrepresented that at the time of the IPO, the Company had agreements with "commercial payors" when the Company only had agreements with PBMs and no insurance companies. (SAC ¶ 136(i).)

Plaintiff fails to demonstrate that a reasonable investor would plausibly find these projections misleading. "[A]n investor reads each statement within a [registration statement], whether of fact or of opinion, in light of all its surrounding text, including hedges, disclaimers, and apparently conflicting information." *Omnicare*, 575 U.S. at 190. The Registration Statement provided several disclaimers about the state of coverage. The Prospectus specifically stated that "[i]f third-party payors do not provide adequate coverage and reimbursement for the use of gammaCore, we will be unable to generate significant revenues." (Offering Documents at 14.) Further, the Prospectus states that

> [w]hile some commercial payors may provide coverage under their pharmacy benefit plans, other payors, including governmental and private insurers, may not be willing or authorized to provide coverage for our therapy under pharmacy plans that more commonly cover prescription drug products.

(*Id.* at 128.)

Plaintiff claims, however, that gammaCore was not covered by any insurer when the Registration Statement was filed. (Opp'n Br. at 8.) In the Court's August 13, 2021 dismissal opinion, the Court found that the Registration Statement's disclosure about "the fact that electroCore's access negotiations were progressing did not suggest that gammaCore was covered by insurers at the time of the IPO." (ECF No. 56 at 15.) Yet, Plaintiff makes the same allegation that electroCore misrepresented that it had agreements with insurance companies at the time of the IPO.

Plaintiff's assertion that the "agreements with commercial payors" implies agreements with insurance companies (SAC ¶ 136(i)–(ii)) also does not convince the Court of a

misrepresentation. The SAC acknowledges that the Prospectus distinguished between its use of the umbrella term "commercial payor," which encompasses PBMs as well as insurance companies and used the more specific term. (SAC ¶ 75; Offering Documents at 4, 5, 96, 129, 130.) Accordingly, the SAC fails to adequately plead a material misrepresentation of the type of payor agreements electroCore had in place.

2. CVS Agreement

Defendants next argue that Plaintiff's allegation that the Prospectus implied that the main PBM agreement was already effective is inconsistent with the actual text of the Prospectus. (Moving Br. at 13.) Defendants additionally argue that the Offering Documents did not misrepresent the number of commercial lives that the Company had access to, given that the Prospectus specifically stated that electroCore "'believe[d], based on [their] estimates' that the agreements '[would] provide' for the reimbursement" they anticipated. (*Id.* at 14 (citing Offering Documents at 97–98).) Further, Defendants contend that the "7 million lives at most" allegation (SAC ¶ 81) derives from was CW3's disagreement with electroCore's business strategy. (*Id.* at 14.) Defendants maintain that the alleged omission, that gammaCore would not be on the template formulary and the coverage would require a prescription from a neurologist "also do not render anything in the Prospectus misleading, and have already been rejected by the Court." (*Id.* at 15.) Defendants argue that Plaintiff's case "boils" down to allegations of electroCore's failure to disclose facts that would have potentially undermined Defendants' optimistic projections, and such a disclosure is not required. (*Id.* At 17.)

In opposition, Plaintiff claims that the SAC alleges new facts demonstrating the falsity of Defendants' statements that they believed the CVS agreement with provide for 17 million commercial lives at the time of the IPO or after. (Opp'n Br. at 11.) Plaintiff contends that CW3

explained that electroCore received a determination in the beginning of 2018 that the CVS contract provided access to 7 million lives at most. (*Id.* at 12.) Plaintiff claims that the number of covered lives is not a projection but rather a verifiable fact based on the CVS agreement and CVS's offered coverage. (*Id.*) Plaintiff additionally argues that Defendants' usage of "we believe" does not save them either because Defendants received a determination from CVS that less lives would be covered due to gammaCore not being on CVS's formulary. (*Id.* at 13.) Plaintiff contends that the language "will provide" and "will shortly have access to . . . implies an immediate or near immediate effect, ***not*** six months to one year." (*Id.* at 16.)

In reply, Defendants reiterate that the text of the Prospectus indicates that "[a]greements . . . are in place that ***we believe, based on our estimates***, ***will provide*** for reimbursement for gammaCore as a pharmacy benefit for approximately 17 million commercial lives, including a contract with a large PBM that ***we believe, based on our estimates***, will initially cover 15 million commercial lives." (Reply Br. at 3 (citing Offering Documents at 130) (emphasis in original).) Defendants contend that an opinion "is not misleading just because external facts show the opinion to be incorrect." (*Id.*)

Plaintiff's claims as to the CVS agreement boil down to three points: (1) electroCore misrepresented the number of commercial lives it would have access to pursuant to the CVS agreement (SAC ¶ 134), (2) electroCore omitted material adverse information regarding the restrictions in the CVS agreement (*Id.* ¶¶ 86–87, 202), and (3) electroCore omitted material adverse information regarding the timing of the CVS agreement (*Id.* ¶ 181).

Plaintiff relies on CW3 as proof of the misrepresentations regarding the CVS agreement. The SAC alleges that CW3 explained that electroCore

> originally thought gammaCore would be included in CVS's template formulary giving electroCore access to millions of patients,

> but later – sometime in the beginning of 2018 – received a 'determination' from CVS and 'when they told us what the contract really meant, [it] was significantly different than how we read it[.]' . . . Instead of access to millions of lives, gammaCore was not 'on [CVS's] template formulary' and 'at best' electroCore would have access to a 'few million lives.'

(*Id.* ¶ 79.)

CW3 bases her conclusion that electroCore knew that the CVS agreement would only cover 7 million lives on the contention that CVS's position was that if one of its managed care plans approached CVS and said it wanted to include gammaCore as a pharmacy benefit, then CVS would cover it for them. (*Id.* at ¶ 81.) According to the SAC, CW3's claim that the CVS agreement would only cover 7 million lives, was a mere opinion. An opinion, however, is not misleading just because external facts show the opinion to be incorrect. *Omnicare, Inc.,* 575 U.S. at 188.

Further, the Prospectus, specifically indicated that electroCore "*believe[d], based on [their] estimates*" that the agreements "*will* provide for reimbursement or gammaCore as a pharmacy benefit for approximately 17 million commercial lives, including a contract with a large PBM that *[they] believe[d], based on [their] estimates*, would initially cover 15 million commercial lives." (Offering Documents at 130 (emphases added).) The Prospectus makes no misrepresentation as to the amount of anticipated commercial lives the CVS agreement would cover.

Plaintiff additionally claims that the Registration Statement omitted material adverse information regarding the restrictions in the CVS agreement. (Opp'n Br. at 14.) The Court has already held, however, that due to the Prospectus's disclaimers (*see* Offering Documents at 14 ("[m]any third-party payors do not currently cover VNS for any indications other than epilepsy because they have determined all other VNS modalities to be investigational or experimental"); *see also id.* at 15 (disclosing that "no uniform policy of coverage and reimbursement for

[gammaCore] exists among third-party payors" and, "[t]herefore, coverage and reimbursement for [gammaCore] can differ significantly from payor to payor")) the Prospectus does not "imply that electroCore's payor agreements covered gammaCore without limitations." (ECF No. 56 at 15.)

Additionally, CW3 alleges that "sometime in the beginning of 2018, electroCore received a "determination" from CVS and gammaCore was not on CVS's "template formulary." (SAC ¶¶ 79, 81.) Further, CW3 claims that as of January 2019, electroCore did not have any agreements in place with insurance companies. (*Id.* ¶ 91.) The Prospectus, however, does not indicate that electroCore had any agreements in place at the time of the IPO. Further, nothing within the SAC indicates that the CVS contract contradicted electroCore's estimate of the number of lives that would be covered prior to the IPO.

Accordingly, the SAC fails to plead a material representation as to the CVS agreement.

3. Physician Acceptance

Plaintiff's allegations that the Prospectus made false statements or material omissions concerning physicians' acceptance of gammaCore is essentially unchanged from her previous Complaint. The Second Amended Complaint alleges that physicians and commercial payors did not find gammaCore's clinical data compelling because the ACT 1 and ACT 2 trials did not meet their primary endpoint. (SAC ¶¶ 93, 106, 138(i).) Plaintiff, however, relies on the on the same confidential witness accounts as she did in the prior Complaint. Further, the Prospectus discloses the risks that some might consider the data insufficient. (*See* Offering Documents at 4, 14–15.) The Court already determined that the "Registration statement's disclaimers about barriers to physical acceptance are more forceful than any boasts on that score." (ECF No. 56 at 15–16.) Accordingly, the Court finds that the SAC fails to plausibly allege a material misrepresentation as to "physician acceptance."

4. Material Barriers to Additional Coverage

Defendants next argue that the SAC fails to sufficiently allege that the Prospectus made false claims about electroCore's financial performance. (Moving Br. at 19.) Defendants assert that the SAC contends that the Prospectus failed to disclose that the voucher program did not accomplish part of its intended purpose. (*Id.*) Defendants contend that it is not required to list every concern every employee has regarding its business strategy in its Offering Documents. (*Id.* at 20.) Defendants maintain that the Prospectus fully disclosed the risks and that the Company had a history of significant losses. (*Id.*) Defendants argue that any argument that the Prospectus did not discuss electroCore's financial difficulties ignored its extensive disclosures. (*Id.* at 20–21.)

In opposition, Plaintiff argues that Defendants failed to disclose that the gammaCore device failed to meet the requirements for an HSPCS E-Code at the time of the IPO. (Opp'n Br. at 17.) Plaintiff additionally argues that the change in voucher program structure was a material actionable omission. (*Id.* at 19.)

In reply, Defendants argue that as to Plaintiff's voucher program argument, electroCore is not required to "denigrate their own products or business plans or strategies," (Reply Br. at 8 (citing *Exkae Ltd. v. Domo, Inc*., 2020 WL 7352735, at *7 (D. Utah Dec. 15, 2020).) Defendants additionally contend that the Company extensively disclosed the risks related to obtaining coverage, and the Court already held that the Prospectus does not "suggest that electroCore was necessarily eligible for certain diagnostic codes." *Id.*

The SAC contends that the Prospectus did not disclose CW's criticism that that the voucher program did not accomplish part of its intended purpose, because "voucher program changes in early 2018 bypassed the insurance companies so potential payers never saw the demonstrated

demand for gammaCore, making it less likely for them to agree to coverage." (SAC ¶¶ 116–18, 136(v)(c).) Businesses, however, are bound to have employees that disagree with its strategies. These opinions, however, are generally not actionable. *See Omnicare*, 575 U.S. at 185. The criticism that the voucher program did not accomplish its intended purpose, therefore, is not a misleading omission from the Prospectus.

Further, Plaintiff's allegation that electroCore omitted the fact that gammaCore was ineligible for certain codes, which would make it more difficult for the Company to find coverage, also fails. The Company disclosed its difficulty and risks of obtaining insurance coverage. The Court further had already held that the Prospectus does "not suggest that electroCore was necessarily eligible for certain diagnostic codes." (ECF No. 56 at 15.) Accordingly, the SAC fails to sufficiently plead a material misrepresentation or omission as to its barriers to obtaining coverage.

5. The Risk Disclosures

Plaintiff argues in opposition that the risk disclosures were also materially false and misleading. (Opp'n Br. at 19.) Plaintiff asserts that it is "not sufficient to warn investors about potential, future contingency and omit to disclose that . . . that contingency had already occurred and was continuing. (*Id.* at 20.) Plaintiff claims that the Registration statement's indication that "many third-party payors do not currently cover" gammaCore because it is "experimental or investigational," does not "insulate Defendants from the failure to disclose that, as of the IPO, every insurer contacted had refused to cover gammaCore. (*Id.*) Plaintiff argues that the risk disclosures were insufficient to disclose the real risks. (*Id.* at 21.)

In reply, Defendants contend that Plaintiff fails to identify any risk disclosure that was materially misleading. (Reply Br. at 9.)

Plaintiff claims that electroCore failed to obtain adequate coverage and failed to mention code ineligibility. (Opp'n Br. at 16–17, 20–21.) The Prospectus, however, did not suggest that adequate coverage was in place. Further, the Prospectus adequately warned that electroCore "only recently began commercializing" gammaCore and electroCore believed that it will have access to an estimated 17 million covered lives. (Offering Documents at 6, 25.)

Plaintiff additionally claims that the Prospectus's disclosure that third-party payors may not agree to cover gammaCore (Offering Documents at 15) is materially misleading because electroCore already knew that "few to no" third-party payors would cover the product. (Opp'n Br. at 20–21.) The SAC, however, fails to allege that electroCore already knew that "few to no" third party payors would cover gammaCore.

Further, Plaintiff contends that "without the HCPCS codes, no insurer would agree to cover gammaCore." (Opp'n Br. at 20.)[4] The SAC, however, claims that CW3 stated that the lack of codes makes it "more difficult" to reach agreements with third-party payors. (SAC ¶ 109.)

Plaintiff additionally fails to plead a violation of Item 303 or 503 of Regulation S-K. The Court already held that the disclosure of risks about payor coverage were "at the level of specificity required by item 503(c)." (ECF No. 56 at 20.)

Accordingly, the SAC fails to sufficiently allege a material misrepresentation as to the risk disclosures.

Because the SAC fails to sufficiently plead a misrepresentation within the Offering Documents, Counts One and Two of the SAC will be dismissed without prejudice.

[4] Plaintiff does not define the term "HCPCS Codes." According to the Centers for Medicare & Medicate Services, "HCPCS" refers to "Healthcare Common Procedure Coding System." https:\\www.cms.gov (last visited July 11, 2023).

B. Count Three: Violation of Section 15 of the Securities Act

Section 15 of the Securities Act provides for joint and several liability on the part of one who controls a violator of Section 11 or Section 12. 15 U.S.C. § 77o; *see In re Adams Golf*, 381 F.3d at 273 n. 3. Because the Court has already determined that the SAC fails to sufficiently pleas a Section 11 or 12 violation, the Court will also dismiss Count Three without prejudice.

C. Count Four: Violations of Section 10(b) of the Securities Exchange Act and SEC Rule 10b-5

Section 10(b) of the Securities Exchange Act prohibits the "use or employ[ment], in connection with the purchase or sale of any security[,] . . . [of] any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe." 15 U.S.C. § 78j(b). Pursuant to its authority under § 10(b) of the Securities Exchange Act, the SEC promulgated Rule 10b-5, making it unlawful for any person:

> (a) To employ any device, scheme, or artifice to defraud,
>
> (b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or
>
> (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5. "To adequately allege a § 10(b) securities fraud claim, a plaintiff must plead (1) a material misrepresentation or omission, (2) scienter, (3) a connection between the misrepresentation or omission and the purchase or sale of a security, (4) reliance upon the misrepresentation or omission, (5) economic loss, and (6) loss causation." *In re Hertz Glob. Holdings Inc*., 905 F.3d 106, 114 (3d Cir. 2018) (internal quotation marks omitted).

Scienter is "a mental state embracing intent to deceive, manipulate, or defraud," *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 319 (2007), and "requires a knowing or reckless

state of mind," *Avaya*, 564 F.3d at 252. Under the PSLRA, a plaintiff must "state with particularity facts giving rise to a strong inference" of scienter. 15 U.S.C. § 78u-4(b)(2). A complaint adequately pleads a strong inference of scienter "only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Tellabs*, 551 U.S. at 324. "[A] plaintiff does not need to come forward with 'smoking-gun' evidence to meet the PSLRA's pleading requirements." *Hertz*, 905 F.3d at 114 (quoting *Tellabs*, 551 U.S. at 324). "Rather, . . . courts must analyze the complaint holistically to determine whether its allegations, 'taken collectively, give rise to a strong inference of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard.'" *Id.* (quoting *Tellabs*, 551 U.S. at 323). "Group pleading" is impermissible to plead scienter under the PSLRA. *Winer Fam. Tr v. Queen*, 503 F.3d 319, 335–37 (3d Cir. 2007). Further, unsubstantiated assumptions and "blanket" or "catch all" allegations are insufficient in the Third Circuit. *California Pub. Employees' Ret. Sys. v. Chubb Corp*., 394 F.3d 126, 144–45 (3d Cir. 2004).

Defendants argue that the SAC "offers nothing to correct the First Amended Complaint's failure to plead facts supporting a strong inference of scienter." (Moving Br. at 28.) Defendants contend that Plaintiff fails to distinguish between the defendants or to state with particularity facts giving rise to a strong inference that each defendant acted with scienter. (*Id.* at 29.) Defendants argue that Plaintiff's group pleading is impermissible to plead scienter under the PSLRA. (*Id.* at 30.)

In opposition, Plaintiff argues that scienter can be satisfied by alleging motive and opportunity, or facts that constitute circumstantial evidence of either reckless or conscious behavior. (Opp'n Br. at 30.) Plaintiff contends that Defendants had actual knowledge and/or recklessly disregarded contradicting facts. (*Id.*) Specifically, Plaintiff insists that Amato, Vraniak,

and J. Errico knew or recklessly disregarded that, regardless of the number of lives technically covered by the CVS agreement, there were significant and undisclosed barriers to coverage that would affect electroCore's revenue stream. (*Id.* at 31.) Plaintiff argues that Amato, Posner, Vraniak and J. Errico spoke publicly in detail about the CVS contract and continuing payer negotiations, including responding to specific analyst questions are enough to infer scienter. (*Id.* at 33.) Further, Plaintiff asserts that even where the SAC does not plead direct knowledge, "it is replete with circumstantial evidence and allegations under the core operations doctrine." (*Id.* at 34.) Plaintiff additionally argues that the SAC's motive allegations support scienter. (*Id.* at 36.)

In reply, Defendants reiterate that a strong inference of scienter is not pled against Exchange Act Defendants. (Reply Br. at 13.) Defendants argue that the allegations of Amato, Posner, and J. Errico are mere allegations of knowledge of the business and without more, is insufficient to infer scienter. (*Id.*) Defendants further contend that the SAC fails to plead motive.

A Section 10(b) claim "cannot survive a motion to dismiss unless it is supported by factual allegations sufficiently demonstrating each defendant's role in the alleged fraud and his or her state of mind in committing such a violation." *In re Merck & Co., Inc. Sec., Derivative, & ERISA Litig*., MDL No. 1658, 2011 WL 3444199, at *19 (D.N.J. Aug. 8, 2011) (citing *Winer Fam. Tr. v. Queen*, 503 F.3d 319, 337 (3d Cir. 2007)).

Here, the SAC alleges that Defendants Cox and Ondra Amato, Posner, Vraniak, and J. Errico "would all have known there were no insurance agreements in place." (SAC ¶ 92; *see also Id.* ¶¶ 77, 238.) However, knowledge that electroCore did not have agreements in place with insurance companies does not show scienter because the Prospectus makes no representation that insurance company agreements were, in fact, in place.

Plaintiff additionally claims that Amato, Posner, Vraniak and J. Errico "publicly admitted to having intimate knowledge of the business" and that "updates on FDA communications were presented to senior management and the Board weekly." (Opp'n Br. at 2–3, 31–33.) Mere allegations of their knowledge of the business, without more, does not prove scienter. *See Rahman v. Kid Brands, Inc*., 736 F.3d 237, 247 (3d Cir. 2013).

Further, the SAC fails to plead sufficient allegations to prove motive. Motive allegations must be "cogent and compelling" to sufficiently plead an inference of scienter. *Tellabs, Inc.,* 551 U.S. at 324. Plaintiff argues that because of electroCore's cash needs through the second quarter of 2019, electroCore needed a successful IPO in order to survive. (Opp'n Br. at 36.) Such an allegation, however, is not pled in the SAC and Plaintiff fails to plead in the SAC that electroCore was unable to raise funds by any other means.

With respect to the remainder of the Exchange Act Defendants (T. Errico, Atieh, Colucci, Moody, and Tullis), the SAC lacks any allegation of sufficient knowledge to support a finding of scienter.

Accordingly, the SAC lacks sufficient allegations for scienter, and therefore Plaintiff fails to state a claim in Counts Four and Five. Counts Four and Five will be dismissed without prejudice for this reason.

V. CONCLUSION

For the reasons stated above, the Court will GRANT the Motion and DISMISS the Second Amended Complaint WITHOUT PREJUDICE. The Court will also permit Plaintiff another opportunity to plead her claims by granting leave to file a Third Amended Complaint within 30 days. Given Plaintiff's two prior unsuccessful attempts, however, failure to remedy the defects

identified by the Court herein may result in dismissal of her claims with prejudice on a subsequent motion to dismiss.

Date: July 13, 2023

s/ Zahid N. Quraishi
ZAHID N. QURAISHI
UNITED STATES DISTRICT JUDGE